REMARKS

Claims 9, 10 and 15 have been canceled without prejudice to, or disclaimer of, the subject matter contained therein. Applicants maintain that the cancellation of a claim makes no admission as to its patentability and reserve the right to pursue the subject matter of the canceled claims in this or any other patent application. Accordingly, Claims 1-8, 11-14, and 16-20 are presented for examination.

Correction of Inventorship under 37 CFR §1.48(b)

21. Applicant requests that several inventors be deleted, as these inventors' inventions are no longer being claimed in the present application as a result of prosecution. The fee as set forth in § 1.17(i) is submitted herewith.

Information Disclosure Statement

The Examiner requested that Applicants provide further information regarding the BLAST results included in the Information Disclosure Statement submitted Sept. 12, 2002. Applicants submit herewith a new Information Disclosure Statement providing the accession numbers, sequences, and publication dates of the sequences identified in the BLAST search.

Claim Objections

Claims 1-20 were objected to for reciting figure numbers. These claims have been amended to remove the figure numbers.

Priority

The PTO has stated that because the claimed nucleic acids have no utility, the priority under 35 U.S.C. § 120 is set at the instant filing date, May 8, 2002. Applicants have previously listed the priority information for the instant application in a Preliminary Amendment mailed September 4, 2002. The preliminary amendment states that the instant application is a continuation of, and claims priority under 35 U.S.C. § 120 to, US Application 10/006867 filed 12/6/2001, which is a continuation of, and claims priority under 35 U.S.C. § 120 to, PCT Application PCT/US00/23328 filed 8/24/2000, which is a continuation-in-part of, and claims priority under 35 U.S.C. § 120 to PCT/US00/14042 filed 5/22/2000, which is a continuation-in-part of, and claims priority under 35 U.S.C. § 120 to, US Application 09/403297 filed 10/18/1999, now abandoned, which is the National Stage filed under 35 U.S.C. § 371 of PCT

Application PCT/US99/20111 filed 9/1/1999, which claims priority under 35 U.S.C. § 119 to US Provisional Application 60/099812 filed 9/10/1998.

Applicants submit that for the reasons stated below, the claimed nucleic acids have a credible, substantial, and specific utility. The sequences of SEQ ID NO: 51 and SEQ ID NO: 52 were first disclosed in Figure 1 and Figures 2A and 2B of US Provisional Application 60/099812 filed 9/10/1998. The data in Example 18 (Tumor Versus Normal Differential Tissue Expression Distribution), relied on in part for the utility of the claimed nucleic acids, were first disclosed in PCT Application PCT/US00/23328 filed 8/24/2000, on page 93, line 3, through page 96, line 35.

Rejections under 35 U.S.C. §101

The Examiner asserts that the claimed invention lacks a specific, substantial and credible utility. In particular, the Examiner asserts that there is no discussion of the structure of the protein encoded by the claimed nucleic acids, nor disclosure of any relationship between such structure and a purported function. The Examiner further asserts that there is no disclosure of any disease or condition in any way related to the claimed nucleic acids nor is there disclosure of any diagnostic assay or analytical assay that could be performed using the claimed nucleic acids. The Examiner also asserts that numerous other uses of the claimed nucleic acids provided in the specification are insufficient to provide a specific, substantial and credible utility. In addition, the Examiner further asserts that the specification is unclear whether PRO1411 stimulates TNF-α production in human blood and that, even if it does stimulate TNF-α production, this activity would not impart utility to the claimed nucleic acids.

As discussed in more detail below, Applicants maintain that, as provided in Example 18 of the application, the nucleic acid of SEQ ID NO: 51 is under-expressed in melanoma relative to normal skin and that this differential expression provides a specific, substantial and credible utility. Applicants note that PRO1411 is not among the proteins which stimulate TNF-α production in human blood.

Utility – Legal Standard

According to the Utility Examination Guidelines ("Utility Guidelines"), 66 Fed. Reg. 1092 (2001) an invention complies with the utility requirement of 35 U.S.C. § 101, if it has at least one asserted "specific, substantial, and credible utility" or a "well-established utility."

Under the Utility Guidelines, a utility is "specific" when it is particular to the subject matter claimed. For example, it is generally not enough to state that a nucleic acid is useful as a diagnostic tool without also identifying the condition that is to be diagnosed.

The requirement of "substantial utility" defines a "real world" use, and derives from the Supreme Court's holding in *Brenner v. Manson*, 383 U.S. 519, 534 (1966) stating that "The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility." In explaining the "substantial utility" standard, M.P.E.P. § 2107.01 cautions, however, that Office personnel must be careful not to interpret the phrase "immediate benefit to the public" or similar formulations used in certain court decisions to mean that products or services based on the claimed invention must be "currently available" to the public in order to satisfy the utility requirement. "Rather, *any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient,* at least with regard to defining a 'substantial' utility." (M.P.E.P. § 2107.01, emphasis added.)

Indeed, the Guidelines for Examination of Applications for Compliance With the Utility Requirement, set forth in M.P.E.P. § 2107 II(B)(1) gives the following instruction to patent examiners: "If the applicant has asserted that the claimed invention is useful for any particular practical purpose ... and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility."

Utility – Evidentiary Standard

An Applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. § 101, "unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope." *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974). See, also *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re Irons*, 340 F.2d 974, 144 USPQ 351 (1965); *In re Sichert*, 566 F.2d 1154, 1159, 196 USPQ 209, 212-13 (CCPA 1977).

Compliance with 35 U.S.C. § 101 is a question of fact. *Raytheon v. Roper*, 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983) cert. denied, 469 US 835 (1984). The evidentiary standard to be used throughout *ex parte* examination in setting forth a rejection is a preponderance of the totality of the evidence under consideration. *In re Oetiker*, 977 F.2d 1443,

1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Thus, to overcome the presumption of truth that an assertion of utility by the applicant enjoys, **the PTO must establish that it is more likely than not that one of ordinary skill in the art would doubt the truth of the statement of utility.** Only after the PTO has made a proper *prima facie* showing of lack of utility does the burden of rebuttal shift to the applicant. The issue will then be decided on the totality of evidence.

Substantial Utility

Applicants have established that the Gene Encoding the PRO1411 Polypeptide is Differentially Expressed in Certain Cancers compared to Normal Tissue and is Useful as a Diagnostic Tool

Applicants submit that the gene expression data provided in Example 18 of the present application are sufficient to establish a specific and substantial utility for the claimed nucleic acids related to the gene encoding the PRO1411 polypeptide.

Applicants submit herewith a copy of a declaration of J. Christopher Grimaldi, an expert in the field of cancer biology, originally submitted in a related co-pending and co-owned patent application Serial No. 10/063,557 (attached as Exhibit 1). In paragraph 5 of his declaration, Mr. Grimaldi states that the gene expression studies reported in Example 18 of the instant application were made from pooled samples of normal and of tumor tissues. Mr. Grimaldi explains that:

> The DNA libraries used in the gene expression studies were made from pooled samples of normal and of tumor tissues. *Data from pooled samples is more likely to be accurate than data obtained from a sample from a single individual.* That is, the detection of variations in gene expression is likely to represent a more generally relevant condition when pooled samples from normal tissues are compared with pooled samples from tumors in the same tissue type. (Paragraph 5) (emphasis added).

In paragraphs 6 and 7, Mr. Grimaldi explains that the semi-quantitative analysis employed to generate the data of Example 18 is sufficient to determine if a gene is over- or underexpressed in tumor cells compared to corresponding normal tissue. He states that any visually detectable difference seen between two samples is indicative of at least a two-fold difference in cDNA between the tumor tissue and the counterpart normal tissue. He also states that the results of the gene expression studies indicate that the genes of interest "can be used to differentiate tumor from normal." He explains that "The precise levels of gene expression are irrelevant; what matters is that there is a relative difference in expression between normal tissue and tumor

tissue." (Paragraph 7). Thus, since it is the relative level of expression between normal tissue and suspected cancerous tissue that is important, the precise level of expression in normal tissue is irrelevant. Likewise, there is no need for quantitative data to compare the level of expression in normal and tumor tissue. As Mr. Grimaldi states, "If a difference is detected, this indicates that the gene and its corresponding polypeptide and antibodies against the polypeptide are useful for diagnostic purposes, to screen samples to differentiate between normal and tumor."

Applicants maintain that the higher expression levels of the claimed nucleic acids in normal skin tissue compared to melanoma renders the claimed nucleic acids useful as a diagnostic tool for cancer and for producing the PRO1411 polypeptide, which can be used to generate antibodies useful as a diagnostic tool for cancer.

Applicants have established that the Accepted Understanding in the Art is that there is a Direct Correlation between mRNA Levels and the Level of Expression of the Encoded Protein

As stated above, the standard for utility is not absolute certainty, but rather whether one of skill in the art would be more likely than not to believe the asserted utility. The working hypothesis among those skilled in the art is that there is a direct correlation between mRNA levels and protein levels.

Applicants submit herewith a copy of a second Declaration by J. Christopher Grimaldi, an expert in the field of cancer biology (attached as Exhibit 2). This declaration was submitted in connection with the related co-pending and co-owned application Serial No. 10/063,557. As stated in paragraph 5 of the declaration, "Those who work in this field are well aware that in the vast majority of cases, when a gene is over-expressed...the gene product or polypeptide will also be over-expressed.... This same principal applies to gene under-expression." Further, "the detection of increased mRNA expression is expected to result in increased polypeptide expression, and the detection of decreased mRNA expression is expected to result in decreased polypeptide expression. The detection of increased or decreased polypeptide expression can be used for cancer diagnosis and treatment." The references cited in the declaration and submitted herewith support this statement.

Applicants also submit herewith a copy of the declaration of Paul Polakis, Ph.D. (attached as Exhibit 3), an expert in the field of cancer biology, originally submitted in a related and co-owned patent application Serial No. 10/032,996. As stated in paragraph 6 of his declaration:

> Based on my own experience accumulated in more than 20 years of research, including the data discussed in paragraphs 4 and 5 above [showing a positive correlation between mRNA levels and encoded protein levels in the vast majority of cases] and my knowledge of the relevant scientific literature, it is my considered scientific opinion that for human genes, an increased level of mRNA in a tumor cell relative to a normal cell typically correlates to a similar increase in abundance of the encoded protein in the tumor cell relative to the normal cell. In fact, *it remains a central dogma in molecular biology that increased mRNA levels are predictive of corresponding increased levels of the encoded protein.* (Emphasis added).

Dr. Polakis acknowledges that there are published cases where such a correlation does not exist, but states that it is his opinion that "such reports are exceptions to the commonly understood general rule that increased mRNA levels are predictive of corresponding increased levels of the encoded protein." (Polakis Declaration, paragraph 6).

The relationship between gene copy number and mRNA levels is discussed in the following references. Orntoft *et al.* (*Molecular and Cellular Proteomics*, 1:37-45 (2002)) (submitted herewith as Exhibit 4) studied transcript levels of 5600 genes in malignant bladder cancers which were linked to a gain/loss of chromosomal material using an array-based method. Orntoft *et al.* showed that there was a gene dosage effect and teach that "in general (18 of 23 cases) chromosomal areas with more than 2-fold gain of DNA showed a corresponding increase in mRNA transcripts" (Orntoft at 37, column 1, abstract). In addition, Hyman *et al.* (*Cancer Research*, 62:6240-6245 (2002)) (submitted herewith as Exhibit 5) used CGH analysis and cDNA microarrays to compare DNA copy numbers and mRNA expression of over 12,000 genes in breast cancer tumors and cell lines. They showed that there is "evidence of a prominent global influence of copy number changes on gene expression levels" (Hyman at 6244, column 1, last paragraph).

Additional supportive teachings are also provided by Pollack *et al.* (*PNAS*, 99:12963-12968 (2002)) (submitted herewith as Exhibit 6) who studied a series of primary human breast tumors and found that "[b]y analyzing mRNA levels in parallel, we have also discovered that *changes in DNA copy number have a large, pervasive, direct effect on global gene expression patterns* in both breast cancer cell lines and tumors." (Pollack at 12967 at column 1, emphasis added). Their study found that "62% of highly amplified genes show moderately or highly elevated expression, that DNA copy number influences gene expression across a wide range of

DNA copy number alterations (deletion, low-, mid- and high-level amplification), that on average, a 2-fold change in DNA copy number is associated with a corresponding 1.5-fold change in mRNA levels." (Pollack at 12963, column 1, abstract). This report is particularly persuasive because the high-resolution comparative genomic hybridization analysis used to assess DNA copy number was particularly sensitive.

Together, the declarations of Mr. Grimaldi and Dr. Polakis and the references cited above establish that the accepted understanding in the art is that there is a direct correlation between the level of mRNA and the level of the encoded protein.In light of the lack of support for any argument by the PTO to the contrary, Applicants submit that they have established that it is more likely than not that one of skill in the art would believe that because the PRO1411 mRNA is expressed at a higher level in normal skin tissue compared to melanoma, the PRO1411 polypeptide will also be expressed at a higher level in normal skin tissue compared to melanoma. One of skill in the art would recognize that a protein which is differentially expressed in certain cancer cells compared to the corresponding normal tissue would have utility as a diagnostic tool. Thus, Applicants submit that they have established that it is more likely than not that one of skill in the art would recognize the asserted utility of the PRO1411 polypeptide, and the nucleic acids which encode it, as a cancer diagnostic tool.

Applicants submit that they have therefore established two separate bases for utility of the claimed nucleic acids. The first argument is based on the differential expression of the PRO1411 encoding gene in normal skin tissue compared to melanoma. The second argument is based on the utility of the PRO1411 polypeptides as diagnostic tools, given that it is well-established in the art that there is a correlation between gene expression and protein expression.

The Claimed Nucleic Acids would have Diagnostic Utility even if there is no Direct Correlation between Gene Expression and Protein Expression

Even assuming *arguendo* that, there is no direct correlation between gene expression and protein expression for PRO1411, which Applicants submit is not true, a polypeptide encoded by a gene that is differentially expressed in cancer would **still** have a credible, specific and substantial utility.

In paragraph 6 of the Grimaldi Declaration, Exhibit 2, Mr. Grimaldi explains that:

> However, even in the rare case where the protein expression does not correlate with the mRNA expression, this still provides significant information useful for

> cancer diagnosis and treatment. For example, if over- or under-expression of a gene product does not correlate with over- or under-expression of mRNA in certain tumor types but does so in others, then identification of both gene expression and protein expression enables more accurate tumor classification and hence better determination of suitable therapy.

This conclusion is echoed in the Declaration of Avi Ashkenazi, Ph.D. (attached as Exhibit 7), an expert in the field of cancer biology. This declaration was previously submitted in connection with co-pending application Serial No. 09/903,925. Applicants submit that simultaneous testing of gene expression and gene product expression enables more accurate tumor classification, even if there is no positive correlation between the two. This leads to better determination of a suitable therapy.

This is further supported by the teachings in the article by Hanna and Mornin (attached as Exhibit 8). The article teaches that the HER-2/neu gene has been shown to be amplified and/or overexpressed in 10%-30% of invasive breast cancers and in 40-60% of intraductal breast carcinoma. Further, the article teaches that diagnosis of breast cancer includes testing both the amplification of the HER-2/neu gene (by FISH) as well as the overexpression of the HER-2/neu gene product (by IHC). Even when the protein is not overexpressed, the assay relying on both tests leads to a more accurate classification of the cancer and a more effective treatment of it.

The Applicants have established that it is the general, accepted understanding in the art that there is a positive correlation between gene expression and protein expression. However, even when this is not the case, a polypeptide encoded by a gene that is differentially expressed in cancer would still have utility, as would the nucleic acid which encodes it. Thus, Applicants have demonstrated another basis for supporting the asserted utility for the claimed nucleic acids.

The use of the claimed nucleic acids as probes is disclosed in the specification at Paragraph [0012], Paragraphs [0226]-[0228], Paragraph [0311] and Paragraph [0530]. The use of PRO polypeptides to generate antibodies is disclosed in the specification at Paragraph [0361]-Paragraph [0396] and Paragraph [0493]-Paragraph [0499]. The use of antibodies against the PRO polypeptides as diagnostic tools is disclosed in the specification in Paragraph [0407].

The utility guidelines recognize that the diagnosis of cancer is a credible utility. (See page 5 of the Revised Interim Utility Guidelines Training Materials which provide that use as a diagnostic marker is a credible utility.)

Furthermore, the utility of the claimed nucleic acids as a melanoma diagnostic is specific to the claimed nucleic acids and is not a characteristic of nucleic acids in general.

Finally, melanoma diagnosis is a substantial utility. (See the caveat in Example 12 of the Revised Interim Utility Guidelines Training Materials, pages 69-70, which states that the utility requirement is satisfied where a protein is expressed in melanoma cells but not on normal skin cells and antibodies against the protein can be used to diagnosis cancer.)

Specific Utility

The Asserted Substantial Utilities are Specific to the Claimed Nucleic Acids

Applicants next address the PTO's assertions that there disclosure of any disease or condition in any way related to the claimed nucleic acids nor is there disclosure of any diagnostic assay or analytical assay that could be performed using the claimed nucleic acids.

Specific Utility is defined as utility which is "specific to the subject matter claimed," in contrast to "a general utility that would be applicable to the broad class of the invention." M.P.E.P. § 2107.01 I. Applicants submit that the evidence of differential expression of the PRO1411 gene in certain types of cancer cells, along with the declarations discussed above, provide a specific utility for the claimed nucleic acids.

As discussed above, there are significant data which show that the gene encoding the PRO1411 polypeptide is more highly expressed in normal skin tissue compared to melanoma. These data are strong evidence that the claimed nucleic acids are useful as diagnostic tools for melanoma or for producing the PRO1411 polypeptide, which can be used to generate antibodies useful for diagnosing melanoma. Thus, contrary to the assertions of the PTO, Applicants submit that they have provided evidence associating the gene encoding PRO1411 with a specific disease. This is a specific utility – it is not a general utility that would apply to the broad class of nucleic acids.

Conclusion

Applicants have provided a declaration stating that the data in Example 18 reporting higher expression of the PRO1411 gene in normal skin tissue compared to melanoma, are real and significant. This declaration also indicates that given the relative difference in expression levels, the claimed nucleic acids have utility as cancer diagnostic tools.

Applicants have presented the declarations of two experts in the field along with supporting references which establish that the general, accepted view of those of skill in the art is that there is a direct correlation between mRNA levels and the encoded protein levels. Thus, one of skill in the art would find that it is more likely than not that the PRO1411 protein has utility as a diagnostic tool for cancer, and nucleic acids encoding the polypeptide also have utility as a result.

Applicants have also presented the declarations of two experts in the field, along with supporting references, which establish that even in the anomalous case where there is no positive correlation between gene expression and expression of the encoded protein, the simultaneous monitoring of both is useful for diagnosis and further classification of the cancer.

Applicants have pointed out that the substantial utilities described above are specific to the claimed nucleic acids because the gene encoding PRO1411 is differentially expressed in certain cancer cells compared to the corresponding normal cells. This is not a general utility that would apply to the broad class of nucleic acids.

Thus, given the totality of the evidence provided, Applicants submit that they have established a substantial, specific, and credible utility for the claimed nucleic acids as a diagnostic agent. According to the PTO Utility Examination Guidelines (2001), irrefutable proof of a claimed utility is not required. Rather, a specific, substantial, and credible utility requires only a "reasonable" confirmation of a real world context of use. Applicants submit that they have established that it is more likely than not that one of skill in the art would reasonably accept the utility for the claimed nucleic acids relating to PRO1411 set forth in the specification. In view of the above, Applicants respectfully request that the PTO reconsider and withdraw the utility rejection under 35 U.S.C. §101.

Rejections under 35 U.S.C. §112, first paragraph

Claims 1-20 were rejected on the assertion that one skilled in the art would not know how to use the claimed invention because the claimed nucleic acids lack utility. For the reasons provided above, Applicants maintain that the claimed nucleic acids possess utility.

Claims 1-6, 8-10 and 14-20 were rejected as encompassing subject matter which was not described in such a manner as to convey to one skilled in the art that the inventors had possession of the claimed invention when the application was filed. In particular, the Examiner asserts that

the claims do not require that the claimed polynucleotide encode a particular protein, nor that any protein encoded thereby possess an particular biological activity, nor any particular conserved structure or other disclosed distinguishing feature. Applicants have amended the claims to recite that the claimed nucleic acids are more highly expressed in normal skin tissue compared to melanoma or encode a polypeptide which is more highly expressed in normal skin tissue compared to melanoma.

Claims reciting the "extracellular domain" or the "associated signal sequence" were rejected on the assertion that there is no disclosure that the protein is a transmembrane protein or of any signal sequence. Applicants have deleted the references to the "extracellular domain." Applicants note that Figure 52 discloses that the polypeptide of SEQ ID NO: 52 has a signal sequence at amino acids 1-21.

The Examiner also rejected Claims 1-20 on the assertion that the biological deposit is necessary to enable the claimed invention and that the Applicants have not stated that the deposit will be maintained for a term of at least 30 years and at least 5 years after the most recent request for the furnishing of a sample of the deposit was received by the depository. Applicants do not concede that the biological deposit is necessary to enable the claimed invention, as the sequence of the claimed nucleic acids is provided in the Sequence Listing filed along with the application. However, to address the Examiner's concerns regarding the deposit, Applicants have amended the specification to provide that the deposit will be maintained for a term of at least 30 years and at least 5 years after the most recent request for the furnishing of a sample of the deposit was received by the depository.

Rejections under 35 U.S.C. §112, second paragraph

Claims 1-20 were rejected as being indefinite in reciting the "extracellular domain." Applicants maintain that the amendments herein render these rejections moot.

Claims reciting the "signal peptide" were also rejected as being indefinite. As discussed above, Applicants note that Figure 52 discloses that the polypeptide of SEQ ID NO: 52 contains a signal sequence at amino acids 1-21.

Claim 20 was rejected as being indefinite in reciting "CHO" cells. Applicants have replaced this abbreviation with the definition provided in Paragraph [0296] of the specification.

Claims reciting that the claimed nucleic acids "hybridize" to another sequence or that the nucleic acids hybridize under "stringent" conditions were rejected as being indefinite. Applicants have amended the claims to recite particular hybridization conditions.

Rejections under 35 U.S.C. §102

Claims 1-20 were rejected under 35 U.S.C. §102(e) as being anticipated by Baker et al., (WO 01/68848A2 (PCT/US01/06520), published Sept. 20, 2001 and filed Feb. 28, 2001). Applicants note that the present application claims priority to U.S. Provisional Patent Application Serial No. 60/099812, filed Sept 10, 1998 while the earliest priority date of the cited PCT application is March 1, 2000. In addition, Applicants note that both the present application and WO 01/68848A2 claim priority to PCT/US00/14042 and PCT/US00/23328. Accordingly, Applicants maintain that in view of the foregoing, the cited PCT application is not prior art under 35 U.S.C. §102(e), since it was not filed before Applicants invention of the claimed subject matter.

The Examiner also rejected Claims 1-20 under 35 U.S.C. §102(e) as being anticipated by PreGrant Publication No. US2003/0027275 (U.S. Patent Application Serial No. 10/176918). Applicants note that the present application claims priority to U.S. Provisional Patent Application Serial No. 60/099812, filed Sept 10, 1998 while the earliest priority date of the cited U.S. application is Sept. 16, 1998. Applicants further note that both US2003/0027275 and the present application claim priority to PCT/US99/20111, PCT/US00/14042, and PCT/US00/23328. In view of the foregoing, Applicants maintain that US2003/0027275 is not prior art under 35 U.S.C. §102(e) since it was not filed before Applicants invention of the claimed subject matter.

Conclusion

The present application is believed to be in condition for allowance, and an early action to that effect is respectfully solicited. Applicants invite the Examiner to call the undersigned if any issues may be resolved through a telephonic conversation.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Oct. 1, 2007

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